

Medizym® anti-IA₂ M

ELISA for the quantitative determination of antibodies
against protein tyrosine phosphatase (IA₂)



CE

Product Highlights

- Serological marker for autoimmune diabetes mellitus type 1
- Excellent diagnostic efficiency with high sensitivity and specificity
- Automatable

YOUR RELIABLE PARTNER IN AUTOIMMUNE DIAGNOSTICS

30 Years of Experience, 150 Partners in more than 100 Countries

Antibodies against Protein Tyrosine Phosphatase

and their Importance in the Diagnosis of Diabetes mellitus Type 1

Diabetes mellitus Type 1

Diabetes mellitus type 1 is a chronic autoimmune disease in which the insulin-producing beta cells of the islets of Langerhans in the pancreas are destroyed. The consequence of this destruction is a reduced insulin production, which results in high blood sugar levels as diabetes mellitus. Genetic predispositions and viral infections are considered risk factors, but the exact causes have not yet been fully clarified.



Islet Cell Antibodies

The destruction of the insulin-producing beta cells of the pancreas is based on the presence of islet cell antibodies (ICA), which are directed against different antigens of the pancreatic islet cells, such as glutamic acid decarboxylase (GAD_{65}), tyrosine phosphatase (insulinoma-associated antigen 2, IA_2), the zinc transporter 8 (ZnT8) and against insulin. Islet cell antibodies (ICA) can be detected in 70 – 80 % of patients with diabetes mellitus. The different antibodies usually appear months to years before the occurrence

of elevated blood sugar levels and are therefore also considered important prognostic markers to identify patients with an increased risk of developing diabetes mellitus type 1. The combined detection of antibodies against GAD_{65} , IA_2 , ZnT8 and insulin is considered an important method for diagnosing diabetes mellitus type 1 at the onset of the disease.

Antibodies against Tyrosine Phosphatase (IA_2)

Protein tyrosine phosphatase (insulinoma-associated antigen 2, IA_2) is localized in the granules of pancreatic beta cells. Antibodies against IA_2 can be detected in the majority of patients with diabetes mellitus type 1 and in a large number of individuals in the prediabetic phase. The appearance of antibodies against the protein tyrosine phosphatase IA_2 is correlated with rapid progression of diabetes mellitus type 1.

Publications

- Batstra *et al.* (2001) Prediction and diagnosis of type 1 diabetes using β -cell autoantibodies. Clin. Lab. 47, 497 – 507.
- Lan, M.S. *et al.* (1996) IA_2 , a transmembrane protein of the protein tyrosine phosphatase family, is a major autoantigen in insulin-dependent diabetes mellitus. Proc. Natl. Acad. Sci. USA 93, 6367 – 70.
- Winter, W.E. *et al.* (2002) Immunological markers in the diagnosis and prediction of autoimmune Type 1a diabetes. Clinical Diabetes 20, 183 – 91.

Medizym® anti-IA₂ M – Enzyme Immunoassay for the Determination of Antibodies against Protein Tyrosine Phosphatase (IA₂)

Antigen

The Medizym® anti-IA₂ M immunoassay is based on the use of recombinant human protein tyrosine phosphatase (IA₂).

Calibration

The Medizym® anti-IA₂ M immunoassay is calibrated using the international standard preparation NIBSC code 97/550. Quantitative results are expressed in IU/mL.

Precision

The precision of test results was assessed by the determination of the intra- and interassay variation by the analysis of multiple samples with different antibody activities.

	INTRAASSAY PRECISION		INTERASSAY PRECISION	
	IU/mL	CV (%)	IU/mL	CV (%)
Sample 1	44	6.5	43	4.2
Sample 2	129	4.3	125	2.2
Sample 3	271	5.3	262	2.4

Diagnostic Sensitivity and Specificity

Sensitivity and specificity were assessed by the analysis of 52 pretested positive samples from patients with suspicion of diabetes mellitus type 1 and 87 pretested negative samples from unselected blood donors.

	DIAGNOSTIC PERFORMANCE
Sensitivity	94.2 %
Specificity	93.1 %





Medizym® anti-IA₂ M

Enzyme immunoassay for the quantitative determination of antibodies against protein tyrosine phosphatase (IA₂) in human serum

HIGH QUALITY – MADE IN GERMANY

- Use of recombinant human protein tyrosine phosphatase (IA₂) for a high specificity
- Ready-to-use (exception: wash buffer), color- and barcoded reagents
- Quality assured handling in routine laboratories
- Incubation at room temperature
- Quantitative determination of antibodies against human protein tyrosine phosphatase (IA₂)
- Calibrated with the international WHO standard preparation NIBSC code 97/550
- Results expressed in IU/mL
- Excellent diagnostic sensitivity and specificity
- High precision within the measurement range
- CE marked
- Fully automatable

Product Information

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Order Information

Medizym® anti-IA₂ M

(96 Determinations)

REF 3506

